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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,714	04/09/2004	Mitsuyoshi Okuda	251697US0	9489

22850 7590 10/05/2006

C. IRVIN MCCLELLAND
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
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ALEXANDRIA, VA 22314

EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,714	Applicant(s) OKUDA ET AL.	
	Examiner Hope A. Robinson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 3-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed April 12, 2006 on July 18, 2006, is acknowledged.

Claim Disposition

2. Claims 1-12 are pending. Claims 1-2 are under examination.

Withdrawn-Objection to Claims

3. Previous objection to the claims for clarity of language is withdrawn by virtue of submission of an amendment.

Withdrawn-Specification Objections

4. Previous objections to the specification are withdrawn by virtue of submission of an amendment.

Withdrawn-Abstract Objections

5. Previous objection to the abstract is withdrawn by virtue of submission of an amendment.

Withdrawn-Claim Rejections - 35 USC § 101

6. Previous rejection to claims under 35 U.S.C. 101 is withdrawn by virtue of submission of an amendment.

Withdrawn-Claim Rejections - 35 USC § 112

7. Previous rejections to claims under 35 U.S.C. 112 first and second paragraphs are withdrawn by virtue of submission of an amendment.

Maintained-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sloma et al. (U.S. Patent No. 5,891,701, April 6, 1999).

Sloma et al. teach a protein sequence that is 95% identical to the claimed SEQ ID NO:1 (alkaline protease, see abstract). Sloma et al. teach one of the point mutations recited in the claims, at position 166Gly. Therefore, the limitations of the claims are met by the reference.

Response to Arguments

9. The response filed on July 18, 2006 has been considered, however, is not fully persuasive. Note that the rejections under 35 U.S.C. 102, for the reasons stated above, have been maintained. The response on page 9 state that the rejection over Sloma et al. is without merit over claim 1, but appears to be proper over claim 2. Applicant states that the sequence of Sloma

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et al. does not meet the limitations of claim 1, which requires that the sequence be SEQ ID NO:1.

This argument is not persuasive because claim 1 is directed to an isolated alkaline protease having an amino acid sequence wherein one or more amino acid residues of SEQ ID NO:1 is mutated. The recitation of "having" is the same as "comprising" which means the sequence in the art can be longer than SEQ ID NO:1. The recitation of "one or more" residues in combination with the open language "having" does not limit the mutations to the ones listed. Thus the sequence in the art can have the ones in the list or others. Applicant's statement that all of SEQ ID NO:1 must be present is not accurate as the claim is directed to a mutated SEQ ID NO:1 with minimally the changes referred to in items (a-g). The Sloma et al. reference teaches one of the listed mutations and has some conservative substitutions and substitutions that are not conservative, however, the structure reads on claim 1 base on the open language.

With regard to claim 2, Applicant states that the claim has been amended to recite "95% homology" and that the actual sequence disclosed by Sloma et al. is 94.6% homology, thus Applicant concludes that Sloma et al. fails to anticipate the claimed invention. This argument is not persuasive. Note that the sequence alignment is directed to sequence identity not homology which are different terms. In addition, an alignment is attached to demonstrate 95% sequence identity of the structure disclosed in Sloma et al. with the instant SEQ ID NO:1. Thus for these reasons herein and those stated above the rejection remains.

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Thu Sep 21 17:13:52 2006

align2

Page 1

GenCore version 5.1.9
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OM protein - protein search, using sw model

Run on: September 21, 2006, 17:13:17 / Search time 0.001 Seconds

(without alignments)
278,194 Million cell updates/sec

Title: US-10-820-714A-1

Perfect score: 2247

Sequence: 1 NDVARGIVADVAQSSVGLY.....EVQAVVVPVGPQFSLAIVN 434

Scoring table: BLOSUM62

Gapop 2.0, Gapext 0.5

Searched: 1 seqs, 641 residues

Total number of hits satisfying chosen parameters: 1

Minimum DB seq length: 0

Maximum DB seq length: 200000000

Post-Processing: Minimum Match 0%

Maximum Match 100%

Listing first 1 summaries

Database: 5891701.pep.*

Pred. No. is the number of results predicted by chance to have a
score greater than or equal to the score of the result being printed,
and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	DB ID	Description
1	2134.5	95.0	641	1	US-08-873-479-42 Sequence 42, Appl

ALIGNMENTS

RESULT 1
US-08-873-479-42
Sequence 42, Application US/08873479
Patent No. 5891701
GENERAL INFORMATION:
APPLICANT: Slovic, Alan
TITLE OF INVENTION: Nucleic Acids Encoding A Polypeptide
TITLE OF INVENTION: Having Protease Activity
NUMBER OF SEQUENCES: 57
CORRESPONDENCE ADDRESS:
ADDRESSER: No. 58917010 No. 5891701disk of No. 5891701th America
STREET: 405 Lexington Avenue
CITY: New York
STATE: NY
COUNTRY: USA
ZIP: 10114
COMPUTER READABLE FORM:
MEDIUM TYPE: Diskette
OPERATING SYSTEM: DOS
SOFTWARE: BASIS for Windows Version 2.0
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/873,479
FILING DATE: 12 JUN 1997
CLASSIFICATION: 510
INVENTOR: SLOVIC, ALAN

NAME: Agria, Cheryl H
REGISTRATION NUMBER: 34,086
REFERENCE/DOCKET NUMBER: 5251,000-US
TELECOMMUNICATION INFORMATION:
TELEPHONE: 212-867-0123
TELEFAX: 212-878-9655
FILER:
INFORMATION FOR SEQ ID NO: 42:
SEQUENCE CHARACTERISTICS:
LENGTH: 641 amino acids
TYPE: amino acid
STRANDNESS: single
TOPOLOGY: linear
MOLECULE TYPE: protein
FRAGMENT TYPE: internal
US-08-873-479-42

Query Match 95.0%; Score 2134.5; DB 1; Length 641;
Best Local Similarity 93.6%; Pred. No. 0;
Matches 407; Conservative 19; Mismatches 6; Indels 3; Gaps 3;

Qy	1	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	60
Db	209	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	268
Qy	61	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	120
Db	269	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	327
Qy	121	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	179
Db	328	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	386
Qy	180	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	239
Db	387	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	446
Qy	240	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	299
Db	447	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	506
Qy	300	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	359
Db	507	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	566
Qy	360	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	419
Db	567	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	626
Qy	420	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	
Db	627	NDVARGIVADVAQSSVGLYGGQIVAVDVTGLDVGKNSMHRFPKITYLVALARTN	

Search completed: September 21, 2006, 17:13:17
Job time: 0.001 sec

Conclusion

10. No claims are allowable.

11. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS *HR*

Patent Examiner *9/22/06*

Kathleen M. Kerr
KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER